

Remarks

Reconsideration of this Application is respectfully requested.

Claims 1-10, 15, 16, 22-29, 31-34 and 36-44 are pending in the application, with claim 1 being the sole independent claim. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

I. Claim Rejections Under 35 U.S.C. § 102

Claims 1, 2, 5, 6, 8, 10, 15, 16, 28, 29, 31-33, 36, 40 and 41 were rejected under 35 U.S.C. § 102(b) as being anticipated by Fluka Catalogue No. 86494 ("Fluka"). *See* Office Action, page 2. Applicants respectfully traverse this rejection for the reasons set forth in the previous response (Filed November 23, 2004).

A. Fluka is Not a Proper § 102 Reference

Applicants maintain that there is no indication of the date of publication of the Fluka reference; it therefore cannot be concluded that Fluka is prior art to the currently pending claims.

With respect to the publication date of Fluka, the Examiner stated that:

Careful inspection of the Fluka reference clearly indicates that the original publication of the "Terrific Broth" media formulation was published in 1987 (see the footnotes at the bottom

of the page). Thus, there is a clear publication date for "Terrific Broth" which is more than one-year prior to the filing date of the instant application.

See Office Action, page 3.

The footnotes pointed out by the Examiner simply relate to references that are *cited by* Fluka. The footnotes at best indicate the year in which *the two cited references* were published; they do not provide any indication as to when Fluka itself was published. The most that can be concluded is that Fluka was published sometime after 1989, but there is no indication that Fluka was necessarily published more than one year prior to the effective filing date of the present application. Without a clear indication as to the publication date of Fluka, the rejection under § 102 cannot be maintained.

Applicants also note that the Examiner has not made a rejection based on the references cited by Fluka, and there is no indication as to what is specifically disclosed in these references.

B. Fluka Does Not Teach a Method For Producing a Eukaryotic Cell Culture Medium

Applicants also maintain their position that, regardless of when it was published, Fluka does not teach a method for producing a eukaryotic cell culture medium. With respect to this issue, the Examiner first stated that "the term 'eukaryotic culture medium' refers to an intended use of the culture medium, and therefore does not carry any patentable weight." *See Office Action, page 3.* Applicants respectfully disagree. A person of ordinary skill in

the art, in view of the present specification, would appreciate that the term "eukaryotic," as a modifier of the term "culture medium," is more than a statement of intended use, but rather relates to the constitution of the culture medium. That is, a "eukaryotic culture medium" would be understood to mean a culture medium containing ingredients that render the medium suitable for the cultivation of eukaryotic cells.

Sole independent claim 1 recites "(b) adding amounts of pH-opposing forms of buffer salts to said dry powdered culture medium in the ratio determined in step (a)." The "dry powdered culture medium" is specified in step (a) as being "a eukaryotic dry powdered culture medium." Thus, the claim requires, at the very least, the addition of pH-opposing forms of buffer salts to a *eukaryotic* dry powdered culture medium. Applicants maintain their position that Fluka does not teach the addition of pH-opposing forms of buffer salts to a *eukaryotic* dry powdered culture medium and therefore cannot anticipate claim 1 or any of the claims that depend therefrom.

Fluka lists the following ingredients of "Terrific Broth":

- Protein hydrolyzate NZ-amine;
- Yeast extract;
- Dipotassium hydrogen phosphate; and
- Potassium dihydrogen phosphate.

Dipotassium hydrogen phosphate and potassium dihydrogen phosphate are pH-opposing forms of buffer salts. However, Fluka does not teach adding these compounds to a *eukaryotic dry powdered* culture medium. Fluka does not indicate the order in which the

four above-listed ingredients are combined. Even if, however, the dipotassium hydrogen phosphate and the potassium dihydrogen phosphate were added to a dry mixture containing protein hydrolyzate NZ-amine and yeast extract, such an addition would not fall within the scope of the present claims because the combination of protein hydrolyzate NZ-amine and yeast extract is not a eukaryotic dry powdered culture medium as required by the present claims.

With respect to whether Fluka teaches a method that falls within the scope of the currently presented claims, the Examiner stated that "Terrific Broth medium carries all of the necessary components to support the growth of yeast cells (a nitrogen and carbon source, in the form of the protein hydrolyzate, yeast extract and glycerol), which are eukaryotic cells." *See Office Action*, page 4. Applicants respectfully disagree with this assertion.

Applicants note that glycerol is not a component of Terrific Broth. Rather, glycerol is a liquid ingredient that is added *after* the dry powdered ingredients of Terrific Broth are suspended in water. *See Fluka*, under the heading "Directions". As noted above, the present claims require the addition of pH-opposing forms of buffer salts to a eukaryotic dry powdered culture medium. At best, Fluka implies the addition of pH-opposing forms of buffer salts to protein hydrolyzate NZ-amine and yeast extract. Protein hydrolyzate NZ-amine and yeast extract do not contain a carbon source. The Examiner does not appear to dispute the requirement for a carbon source in culture media. Thus, protein hydrolyzate NZ-amine and yeast extract cannot be regarded as *any type* of culture medium, much less a eukaryotic culture medium as required by the present claims.

Since Fluka does not teach the addition of pH-opposing forms of buffer salts to a eukaryotic dry powdered culture medium, Fluka does not and cannot anticipate the present claims. Applicants respectfully request that this rejection be reconsidered and withdrawn.

II. Claim Rejections Under 35 U.S.C. § 103

Claims 1-10, 15, 16, 22-29, 31-34 and 36-44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 98/36051 in view of Fluka. *See* Office Action, page 4. Applicants respectfully traverse this rejection for the reasons set forth in the previous response (Filed November 23, 2004).

Applicants maintain their position that Fluka is not a proper reference under 35 U.S.C. § 103 because there is no indication of the date of publication of Fluka. *See* discussion above.

Applicants also maintain that the Examiner has not pointed to any particular evidence which indicates that a person of ordinary skill in the art would have been motivated to modify or combine the cited references. According to the Examiner:

the motivation to combine the references comes from the desire to formulate a media composition with a desired pH upon reconstitution of the formulation without the addition of exogenous sources (meaning pH-adjustment after the formulation has been reconstituted). Fike (WO 98/36051) teaches the use of an acid or a base to formulate a automatically pH-adjusting media formulation

(which provides significant cost and time saving effects, as well as limits the chance of contamination; see for example page 38, lines 4-10 of Fike), while Fluka teaches the adjustment can be made using pH-opposing forms of buffer salts instead of an acid or a base.

See Office Action, page 6. Applicants respectfully disagree.

The Examiner has relied on certain statements from WO 98/36051 that allegedly would have motivated a person of ordinary skill in the art to combine WO 98/36051 with Fluka to arrive at a method that falls within the scope of the present claims. Specifically, the Examiner has pointed to the following passage from WO 98/36051:

The time required for the preparation and shipping of the media, media supplement, media subgroup and buffer formulations may be reduced from 6-8 weeks to as little as one day. The automatically pH-adjusting media of the invention also provide significant cost and time savings, and reduce the tendency for introduction of contamination into reconstituted media that may occur during the pH adjustment process according to standard methods using traditional dry powder or bulk liquid media.

See WO 98/36051, page 38, lines 4-10. Based on this passage, the Examiner stated that "[t]he desirability of obtaining a automatically pH-adjusting buffer taught by [WO 98/36051] is what provides the clear and particular motivation to combine the references as obvious variants." See Office Action, page 6 (emphasis in original).

The above-quoted passage from WO 98/36051, however, simply relates to the advantages provided by the invention set out in this reference. According to WO 98/36051, the automatically pH-adjusting media referred to therein provides cost and time savings, and reduces the tendency for the introduction of contamination into reconstituted media. WO 98/36051 does not indicate or suggest that these cited advantages are something that need to be sought after; rather, WO 98/36051 explicitly states that these advantages are already provided by the media set forth therein. A person of ordinary skill in the art would conclude that the "desirability" of obtaining cost and time savings and reducing the tendency for contamination are already provided by the invention of WO 98/36051 itself; there is no reason to modify this reference or to look elsewhere for these advantages.

The Examiner has not pointed to anything in WO 98/36051 (or in Fluka) that would have suggested to one of ordinary skill in the art that the subject matter of WO 98/36051 could or should be improved in any way. The Examiner has simply pointed to statements in WO 98/36051 relating to advantages that are provided by the subject matter therein. The Examiner has misinterpreted these statements as somehow indicating a *desirability of obtaining* the advantages. There is a stark difference between a reference that states that it has solved a particular problem and a reference that indicates that the problem remains to be solved. WO 98/36051 is the former, and it provides no motivation to modify this reference or to combine it with Fluka.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

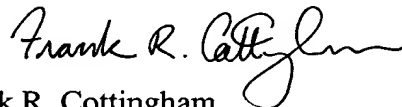
Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

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1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600